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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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N

EXAMINER

HM22/1001

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ART UNIT	PAPER NUMBER
DRAPER, G.	
1646	7

DATE MAILED: 10/01/99

for Restriction

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

Responsive to communication(s) filed on _____.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

ıortened statutory period for response to this action is set to expire 3 month(s), or thirty days, :hever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 36(a).

ɔosition of Claims

Claim(s) 1-9, 14-48, 71, 150 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
Claim(s) _____ is/are allowed.
Claim(s) _____ is/are rejected.
Claim(s) _____ is/are objected to.
Claim(s) 1-9, 14-48, 71, 150 are subject to restriction or election requirement.

ılication Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
The drawing(s) filed on _____ is/are objected to by the Examiner.
The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
The specification is objected to by the Examiner.
The oath or declaration is objected to by the Examiner.

ırity under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

] All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

Certified copies not received: _____.

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

ıchment(s)

Notice of Reference Cited, PTO-892
Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
Interview Summary, PTO-413
Notice of Draftperson's Patent Drawing Review, PTO-948
Notice of Informal Patent Application, PTO-152

1. Part III: Detailed Office Action

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647.

2. Formal Matters:

In view of the extensive number of claims that have been of record, the following represents a summary of the status of the claims:

--With the filing of the application, 207 claims were filed.
--The Pre-Amendment dated 1-25-99 canceled claims 10-12, 49-70, 72-149 and 151-27, thereby leaving claims 1-9, 13-48, 71 and 150 of record.
--A restriction was issued on 10-1-99 in which claims 1-9, 13-48, 71 and 150 were divided into three groups.
--On 12-6-99, applicants elected the method of Group II, claim 71, which was amended. Applicants also stated at page 2 of the Pre-Amendment that claims 208-220 were added, however, a total claims 208-223 were added. Applicant's statement that claims 208-220 were added would appear to be only consistent with the claims that are directed to the elected group. New claims 221-223 are directed to an invention that is distinct from the elected group as set forth below. Thus, this office action is directed to the merits of claims 71 and 208-220.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the elected invention to which the claims are directed. The following title or the like is suggested: "METHODS OF IDENTIFYING OR SCREENING FOR AGENTS THAT BINDS THE OB-Re"

3. Restriction Requirement:

3a. Applicant's election with traverse of Group II, now claims 71 and newly added claims 208-220 in Paper No. 8 of 12/6/99 is acknowledged. The traversal is on the ground(s) that: 35 USC 121 states that restriction can be required if multiple inventions are independent and distinct, and that the inventions of Groups I. II. And III are not independent nor are they distinct inventions; that the inventive concepts of these three Groups are related and therefore are neither independent or distinct as they define a single inventive concept; and finally that there would not be a serious burden on the Examiner to examine each of the three Groups. This is not found

persuasive because most contrary to each of the above positions taken by applicants, the restriction is proper as was previously set forth and even as modified herein.

The traversal is on the ground(s) that two or more inventions must independent (no disclosed relationship between the groups), and distinct (related by capable of separate manufacture, use and patentably distinct) for restriction purposes, wherein applicants have emphasized the definition of these terms as stated in the parenthesis about; further that the restriction is traversed because there is no serious burden on the Examiner based on the searches for the various group. This is not found persuasive because applicants have merely quoted an relied upon the definitions for "independent" and "distinct". But the mere reliance on these definitions alone does not serve to show that the restriction is in error. In fact, MPEP 803 clearly sets forth the guidelines for when a restriction is considered proper and the criteria for restriction between patentably distinct inventions. This section clearly states that a restriction is proper, and this is when the Examiner can show that the inventions are **either independent or distinct** (further noting sections 806.04, and 806.05); thus, the Examiner need not prove that the invention are both independent and distinct.

It is additionally pointed out that the search and examination of each of the groups, which searches and examinations are not co-extensive, are not required one for the other. Thus, most contrary to applicants position that the **search and examination** of each group would indeed pose a serious burden for the examination. In fact, the mere searches for each group would not be identical, and even though there may be some overlap or relatedness, this is not a proper basis for holding the restriction as being improper. Also argued is that a search for one groups would be overlapping and provide useful information about the other groups. However, the fact that some useful information may be obtained in the searches of one group for that of another group, and the fact that their may possible be overlaps in the searches in not a sufficient basis for holding he restriction to be improper, because the search and examination of one groups many not yield all of the necessary information for the other group.

The other reasons enumerated by applicants are not proper reasons for holding that

restriction can not be made between certain groups-especially when the Examiner has set forth proper logic and reasoning consistent with the statutes and the guidance in the MPEP for holding a restriction to be proper.

The requirement is still deemed proper and is therefore made FINAL.

3b. Newly submitted claims 221-223 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: it is further pointed out that although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for multiple/different methods, restriction is deemed to be proper because the methods appear to constitute patentably distinct inventions. The inventive concepts of the newly added method claims, which would now constitutes Group IV, and the methods of Groups II, and Groups III require the use of different steps/methods; elements/agents that are physically and functionally distinct; there are different starting elements and the final outcome/results are different for these different methods that cover various diagnostics and therapeutic methods; and if determined to be patentable they would also be patentably distinct. Furthermore, these methods are not required one for the other, nor does each of the methods require the use of the product.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 221-223 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Objections and 35 USC 112 Rejections:

4a. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 71 and 208-220 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There are several reasons why the claims are rejected under 35 USC 112/2nd paragraph, and they are as follow:

Claim 71 is indefinite and incomplete for failing recite sufficient process steps, elements or

limitation to achieve the claimed method, because the mere statement of "contacting" and "under conditions suitable" does not set forth sufficiently precise limitations. Also, it is not clear how suitable the conditions have to be as this too is a relative term. Therefore, it is suggested that the claims be amended to further define the claimed method.

The term "Substantially the same" in claims 210 and 215 ; and the term "conditions suitable for binding" are relative term which renders the claim indefinite. The term "substantially the same" in relations to clearly identify and setting forth how much variation there is in the amino acid sequence is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since this is a relative term in which both physical and functional limitations have not been set forth to determine how much alike or different the amino acid sequence can be in order to be usable in manner as claimed, the skilled artisan would not know what is intended by such, nor would the scope of such be determinable.

Claims 211 and 216 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. These claims are not further limiting in the statement that the "compound is not previously known to bind...".

Claims 212 and 216 and their dependent claims are prolix because they contain long recitations or unimportant details which hide or obscure the invention, or that the recitation of very long detailed claims setting forth so many elements that invention cannot possibly reside in the combination should be rejected as prolix [See *Ex parte Iagan,* 1911 C.D. 10, 162 O.G. 538 (Comm'r Pat. 1910); and *In re Ludwick*, 4 F.2d 959, 1925 C.D. 306, 339 O.G. 393 (D.C. Cir 1925) respectively]. Additionally, the format of many of the claims comprise double inclusion of an element in members of a Markush groups, where there is overlapping members for alternatives recited in a claim's Markush groups, or where the claim can be read to include the same element twice [For support see *Ex parte White*, 759 O.G. 783 (Bd App 1958; *Ex parte Clark*, 174 UPSQ 40 (Bd App. 1971; *Ex parte Kristensen*, 10 USPQ2d 1701 (Bd. Pat. App. & Inter. 1989)] This

causes the claims to be objectionable and indefinite. Finally, the claims represent an unreasonable number of claim limitations, that are unreasonable in view of the nature and scope of applicants's invention and the state of the art, inasmuch as it relates to confusion of the issue. The Examiner recognizes that there may not be a large number of claims, but this is because applicants have chosen to combined many of these distinct products and/or limitations/embodiment into one claims. However, the issue is still the same, which makes this consistent with the CCPA's position set forth in In re Chandler, 254 F.2d 396, 117 USPQ 361 (1959) and In re Chandler, 319 F.2d 211, 225, 135 USPQ 138, 148 (1963) where it was held that applicant's latitude in stating their claims in regard to number and phraseology employed "should not be extended to sanction that degree of repetition and multiplicity which beclouds definition in a maze of confusion"). Furthermore, such claims, or claim limitations or permutations could be rejected one over the other if they differ only by subject matter old in the art (*Ex parte Whitelaw*, 1915 C.D. 18, 219 O.G. 1237 (Comm'r Pat. 1914), where this doctrine is applied when the claims are unduly multiplied or are substantial duplicates (*Ex parte Kochan*, 131 USPQ 204, 206 (Bd. App. 1961). This is especially true for limitations in claim 212 for the first and second compound and chemical compound. The last sentence of claim 212 does not make clear that the chemical compound being referred to is the first or second. It is strongly suggested that the claims be amended to make them more precise and clear.

6. Prior Art Rejections:

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness

rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 77 and 208-220 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Tartaglia et al (`621), Snodgrass et al (`123 or `098), Caskey et al (`340), Friedman et al (` ) or Chang et al (`424) alone or as combined.

Each of the prior art disclose the cloning and expression of one or multiple forms of the OB-R (see the figures and sequences of each). Also disclosed is that the receptors or cells that express these various forms of the OB-receptor can be used to detect for agents which bind to the receptor, wherein these detectable agents can be other variant forms of the receptor, or they can be for agonist or antagonist (see the entire documents of each). Each of these prior art teach that the assay for such binding agents can be performed by various methods known in the art. With the exception of Chang et al, which discloses an OB-R having an amino acid sequence that is identical that one of the instant claims (see the sequence and attached sequence alignment), the other prior art disclose other variant forms of the receptors. Also not disclosed by each of the prior art is the exact assay methods of the claims. However, the claims recite the use of methods that are well known in the art for assaying bind, with either antibodies or other well known methods.

At the time of the invention, it would have been prima facie obvious to detect for binding agents to the OB-R using any one of the receptors of the prior art, despite the fact that some of the prior art disclose the use of variant forms of the receptor. For example, each of Snodgrass et al teach that the can detect for variant forms of the receptors, which satisfies the claim limitations for a binding compound, but there is also sufficient teachings therein that the detected variants could also be used to detect for other binding agents to the receptor (see the entire documents). In view of the fact that a substantial portion of the Ob-R have identical sequences in the extracelllular domain, one skilled in the art would expect that these forms could be used to detect

for the presence of other variant form of the OB-R and the subsequently use these forms to detect for other binding agents. This would have been both expected and predictable from the prior art because of the sequence identity, and because it was well know at the time of filing that certain variant forms of the OB-R could be detected or is expressed in certain cell type (Also, see the art that is cited as of interest).

It is also pointed out that even though the claims refer to an OB-R of a specific sequence, there is nothing in the claims to suggest that the C-terminal portion of the OB-R is critical for the detection of the binding compounds and the only portion of the OB-R that is used to detect for the binding. Therefore, the claims would have been prima facie obvious from the individual teachings of the prior art, or from the combined teachings.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The other prior art listed on the PTO 892 is cited of interest to show related art.

9. ***Advisory Information:***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to **Garnette D. Draper, Art Unit 1647, whose telephone number is (703) 308-4232.** Examiner Draper can normally be reached Monday through Friday, 9:30 A.M. to 6:00 P.M.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.

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GROUP 1800